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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,506	08/06/2001	Marta Blumenfeld	50.US3.PCT	9451

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,506	BLUMENFELD ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,11,13-15,19,23-25,28,35-37,39,47,48,51 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5, 8, 11, 13-15, 19, 23-25, 28, 35-37, 39, 47, 48, 51, 57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The examiner acknowledges the applicant's cancellation of Claims 6, 7, 9, 10, 12, 16-18, 20:22, 26, 27, 29-34, 38, 40-46, 49-50, and 52-56 in the preliminary amendment dated April 13,2001.

2. Upon further consideration, the previous Restriction/Lack of Unity has been withdrawn in favor of the Restriction/Lack of Unity provided below. Specifically, the transgenic animal and the method requiring a computer have been separated from their previous groups. Moreover, applicant is requested to select a biallelic marker within the selected sequence for examination.

Election/ Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. The claims lack unity because they are drawn to a large number of distinct polynucleotides, each of which constitutes a separate special technical feature. Furthermore, the sequences lack a special technical feature because the prior art teaches other polynucleotide sequences that are isolated from the CNS and that are associated with schizophrenia. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-5, 8, II, 13-15, 19, and 23-24, drawn to an isolated, purified polynucleotide.

Group II, Claim 25, drawn to a non-human host animal or mammal.

Group III, Claims 28, 35-37, 39, 47, 48, drawn to a method of genotyping, estimating the frequency of an allele or haplotype, detecting an association between a genotype or haplotype and a trait, determining whether an individual is at risk of developing schizophrenia.

Group IV, Claim 51, drawn to a computer readable medium.

Group V, Claim 57, drawn to a method for comparing a first sequence to a reference sequence using a computer program.

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4. A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. While the instant claims all are directed to a G713 or 13q31-q33 nucleic acid, it is clear from the art, namely Brennan that said nucleic acid consisting of essentially of a contiguous span of 8-50 nucleotides of anyone of SEQ ID NO: 1-3 and 32-69, wherein said span includes a G713 or 13q31-q33 biallelic marker do not define a contribution over the prior art. First, Brennan teaches every 10 mer nucleic acid affixed to an array. Therefore, Brennan inherently anticipates the claimed invention. Furthermore, based upon the claims as written, it is

unclear what consisting essential of requires such that it is unclear whether the span actually includes a biallelic marker in context, or whether the claim merely requires the presence of an A, C, G, or T in the in the nucleic acid. According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature is a contribution over the prior art. The inventions listed in Group I do not relate to a single general inventive concept because the lack of the same or corresponding special technical feature. The technical feature of Group I is "a nucleic acid consisting of essentially 8 nucleotides wherein said nucleotides includes a biallelic marker" which is shown by Brennan to lack novelty or inventive step and does not make it a contribution over the prior art.

3. Group I, II, IV are directed to inventions which do not share the same technical feature. The inventions of Groups I, II, and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The transgenic animal of Group II is a composition made up of structurally and functionally complex biological systems. The computer readable medium is directed to inorganic materials. Furthermore, the products of Groups I, II, and IV can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the computer readable medium may be used for storing data not related to sequence information or searching the nucleic acid sequence for motifs, predicting potential proteins encoded by the nucleic acid, etc., while

transgenic animals can be used to express different proteins other than G713. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and IV do not share the same technical feature.

Restriction Requirement Applicable to All Groups

In addition, each group detailed above reads on a large number of distinct polynucleotides, each of which constitutes a separate special technical feature. Furthermore, the sequences lack a special technical feature because the prior art teaches other polynucleotide sequences that are isolated from the CNS and that are associated with schizophrenia. The application specifically recites claims drawn to SEQ ID NOs: 1, 2, 3, 4, 6, and 31-39. These sequences may contain a G713 or 13q31-q33-related biallelic marker selected from the group consisting of A1 to A49. Additional claims are drawn to nucleic acids that encode the protein sequences of SEQ ID NOs: 5 and 7. Still further claims are drawn to polynucleotides consisting essentially of sequences B1-B49, C1-C49, D1-D49, E1-E49, and P1-P49. Polynucleotides with different sequences are structurally distinct chemical compounds and are unrelated to one another. Each of these sequences are thus deemed to normally constitute a distinct special technical feature and are therefore subject to a restriction requirement.
The applicants are restricted to a single nucleotide sequence identified by a Sequence ID Number. This nucleotide sequence must be clearly defined with each residue specified without ambiguity. The applicant may choose to define the selected nucleotide

sequence as a nucleotide sequence that encodes a specified polypeptide sequence. Applicant should note that although claiming the nucleotide sequence in these terms is based on the selection of an amino acid sequence, it is the corresponding nucleotide sequence that will be prosecuted on its merits.

With the selection of a single sequence, applicant is requested to select a corresponding biallelic marker within the sequence.

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, not an election of species.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg
Jeanine Goldberg
April 1, 2003

GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600